

DEC 19 2000

K003115

PG. 1 OF 1

10. 510(k) SUMMARY, SAFETY AND EFFECTIVENESS

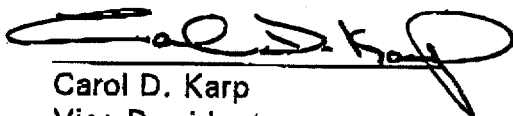
This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21CFR 807.92.

Trade name: ACTIS® Adjustable Constriction Loop
Common name: Constriction Ring (Erectile Dysfunction Device)
Classification name: External Penile Rigidity Device

The ACTIS® Adjustable Constriction Loop is intended to improve penile rigidity in men with erectile dysfunction by restricting penile venous outflow. It is a linear latex tube with an O ring and ball locking unit that allows ease of adjustment to increase or decrease tension. Placement is around the base of the penis.

Directions and diagrams for proper use, care, and recommended duration of application of the ACTIS® device are part of the materials provided to the consumer. The ease of adjustability provides a high degree of safety when used according to the directions.

The ACTIS® Adjustable Constriction Loop is substantially equivalent to the marketed VIVUS ACTIS® (Venous Flow Controller) device. The ACTIS® device proposed for over-the-counter marketing is identical to the prescription device.



Carol D. Karp
Vice President
Regulatory Affairs & Project Management
Phone (650) 934-5224
Fax (650) 934-5212

12-14-00
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2000

Ms. Carol D. Karp
Vice President
Regulatory Affairs & Project Management
VIVUS, Inc.
1172 Castro Street
MOUNTAIN VIEW CA 94040

Re: K003115
ACTIS® Adjustable Constriction Loop
Dated: September 29, 2000
Received: October 02, 2000
Unclassified
Procode: 78 LKY

Dear Ms. Karp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

ATTACHMENT 2

ACTIS®
VIVUS, Inc.

Indications for Use Statement

510(k) Number: K003115

Device Name: ACTIS® Adjustable Constriction Loop

Indications for Use: Improve penile rigidity in men with erectile dysfunction by restricting penile venous outflow.

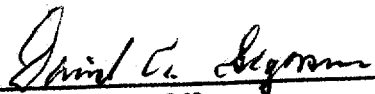
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓


(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K003115